UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA and THE STATE OF TENNESSEE *ex rel.* SUZANNE ALT, MARY BUTNER, DANA BROWN, JEBBIFER PRESSOTTO, JUNE KIMBROUGH, SCOTT STEED and ALLISON CHANCELLOR, Plaintiffs, v. ANESTHESIA SERVICES ASSOCIATES, PLLC d/b/a COMPREHENSIVE PAIN SPECIALISTS, PETER B. KROLL, M.D., JOHN DAVIS, STEVEN R. DICKERSON, M.D., GILBERTO A. CARRERO, M.D., and RUSSELL S. SMITH, D.C., Defendants.	Case No. 3:16-cv-00549 (Consolidated) Hon. Aleta A. Trauger **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

Qui tam Plaintiff-Relator Allison Chancellor ("Relator"), through her attorneys Phillips & Cohen LLP and the Richard Fisher Law Office, on behalf of the United States of America, and the Plaintiff-States of Illinois, Indiana, Iowa, North Carolina, Tennessee, and Virginia (the "Plaintiff-States"), files this Amended Complaint against Anesthesia Services Associates, PLLC, d/b/a Comprehensive Pain Specialists ("CPS"), Peter Kroll, M.D., John Davis, Steven R. Dickerson, M.D., Gilberto A. Carrero. M.D., and Russell S. Smith, D.C., (all collectively, "Defendants"), for violation of the federal False Claims Act, 31 U.S.C. 3729 et seq. and analogous state qui tam statutes, and fraud against private insurers in violation of the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92. The United

States and the State of Tennessee elected to intervene in Relator's *qui tam* allegations from her original complaint. The United States' "Notice of Election to Intervene, And Decline to Intervene, in Parts of this Consolidated Action and to Add Defendants," states with regard to Relator Allison Chancellor's claims that:

> In *United States and the States of Illinois, Indiana, Iowa, Michigan, North Carolina, Tennessee, Virginia ex rel. Alison Chancellor v. Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists et al.*, Case No. 3:19-cv-00102, the United States intervenes in that part of the action that alleges that CPS violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A), (B) & (G), with respect to UDS, genetic and psychological testing, and up-coding. The United States declines to intervene in Counts II-X and the allegations related thereto, as well as the allegations against defendant PhyMed Management LLC d/b/a PhyMed Healthcare Group. The United States informs the Court that at this time it intends to add the Owners of CPS and Davis as additional defendants in the consolidated action based on the same allegations in which it is intervening.

(Dkt. 43 at 2-3.). The State of Tennessee elected to intervene on the same allegations as the United States (Dkt. 44). The other States filed notice that they are not intervening in the action at this time.

I. RELATOR ADOPTS THE UNITED STATES' AND STATE OF TENNESSEE'S COMPLAINT IN INTERVENTION

1. Relator hereby adopts the Complaint in Intervention filed in this action by Plaintiffs the United States and the State of Tennessee. Relator incorporates herein by reference all of the allegations in the United States' and the State of Tennessee's Complaint in Intervention filed July 22, 2019 (Dkt. 65), as well as all of the claims for relief asserted therein under the False Claims Act and the Tennessee Medicaid False Claims Act, as though fully set forth herein.

2. Relator hereby incorporates herein the allegations made by the United States and the State of Tennessee in Counts I, II, III, and IV of the United States' and the State of Tennessee's Complaint in Intervention filed July 22, 2019 (Dkt. 65).

3. In addition to the allegations and claims that Relator adopts from the aforesaid Complaint in Intervention, Relator sets forth allegations in support of her claims under the federal False Claims Act, including her claim for relief for employment retaliation under 31 U.S.C. 3730(h) and the *qui tam* statutes in Illinois, Indiana, Iowa, North Carolina, and Virginia as well as her claim for relief under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92.

II. INTRODUCTION

4. This is an action to recover damages and civil penalties on behalf of the United States Government (the "United States" or the "Government") and the Plaintiff-States, arising from false and/or fraudulent statements, records, and claims made and/or caused to be made by the Defendant and/or their agents and employees in violation of the federal False Claims Act, 31 U.S.C. § 3729, *et seq*., and similar state statutes, and the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).

5. Relator brings this *qui tam* case to redress the knowing submission of false or fraudulent claims by Defendants. Founded in 2005, CPS is a Tennessee-based company that owns and operates 53 pain management clinics in ten states.

6. The false or fraudulent claims fall into at least three categories: (1) claims submitted to federal and state governments, and private insurers in Illinois, for unnecessary urine drug testing ("UDT"), unnecessary pharmacogenetic testing ("PGT"), and unnecessary psychological testing, (2) claims submitted with "upcoded" Evaluation and Management codes that misrepresent the level of service provided the patient during an office visit, and (3) claims provided for referrals obtained in violation of the Anti-Kickback Statute.

7. Starting around 2011 and 2012, CPS initiated an aggressive business model to acquire established pain management practices and to assume business operations for those practices while the physicians who previously owned the practices, and other medical staff, provide clinical pain management services to patients.

8. CPS owned its own laboratory facilities and requires physicians and other clinical staff to order and to refer tests to CPS laboratories.

9. CPS submitted claims for pain management services including office visits, laboratory, and other testing services, directly to federal, state, and private health insurers, including Medicare and Medicaid.

10. In 2014, CPS acquired a pain management clinic, Piasa Pain Clinic, in Alton, Illinois from two physicians: Dr. Thomas Brummett and Dr. Wynndel T. Buenger.

11. By acquiring physician pain practices, CPS obtained access to the physician's existing patients and provides operational and administrative support with a goal of expanding the value of the practice.

12. Based upon Relator's direct observation and independent research, it appears that, in at least some locations, including Alton, Illinois, CPS offered favorable deals for physicians by providing revenue through sizeable rent payments for space owned or leased by physicians, and not utilized by CPS, and other similar remuneration.

13. At each of its pain clinics, CPS sought to increase revenues from federal, state and private insurers by requiring, as a matter of standardized policy and practice, that patients receive a high number of laboratory tests, including repeated drug screens and psychological testing, and that the laboratory testing is performed at CPS's laboratories.

14. To achieve that end, CPS managers exerted control over clinical and non-clinical staff, including physicians and other medical providers, by inducing and coercing compliance with "CPS Standards" mandating frequent, and often unnecessary urine drug

screens, unnecessary genetic testing, and repetitive and often unnecessary psychological tests.

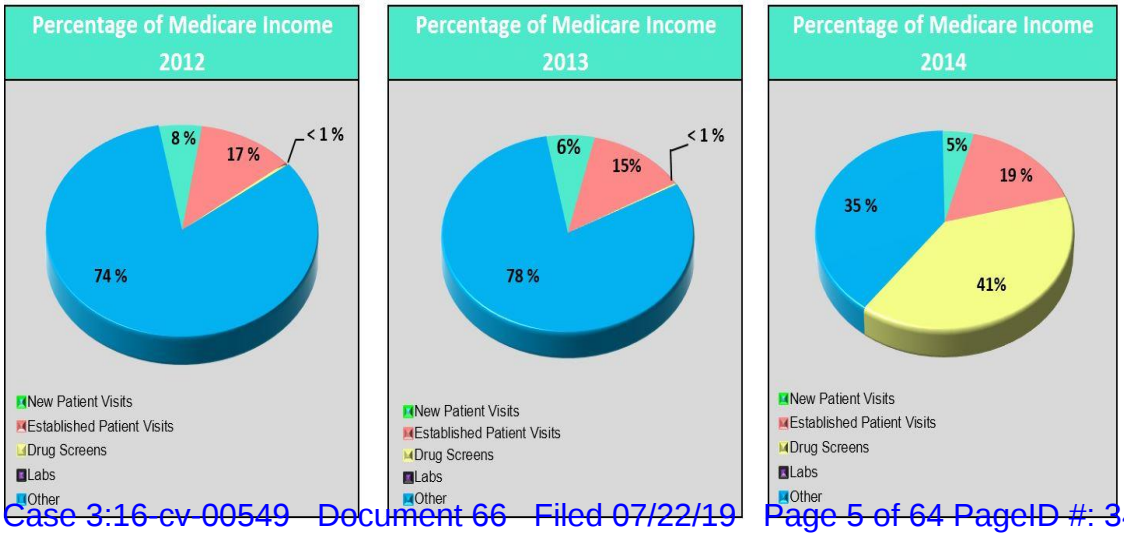
15. All of these policies and practices elevated CPS's corporate revenue goals above the individualized medical needs of pain patients and the independent exercise of medical judgment by trained physicians and other medical providers in ordering laboratory tests and other services.

16. As a result of CPS's aggressive testing policies and practices, utilization for drug tests and other laboratory testing increased significantly at CPS clinics, relative to the pain practices before acquisition, despite no dramatic increase in patient census and as compared to those same physicians' previous utilization of laboratory tests.

17. For example, in 2012 and 2013, before CPS acquired the Alton, Illinois practice in June 2014, according to Medicare data, urine drug screens ordered by Dr. Brummett constituted approximately 1% of the Medicare payments paid to his practice. In 2012, Dr. Brummett received only $1,833.40 for urine drug screens on 79 Medicare patients. In 2013, he received slightly over $1,000 for urine drug screens on 56 patients.

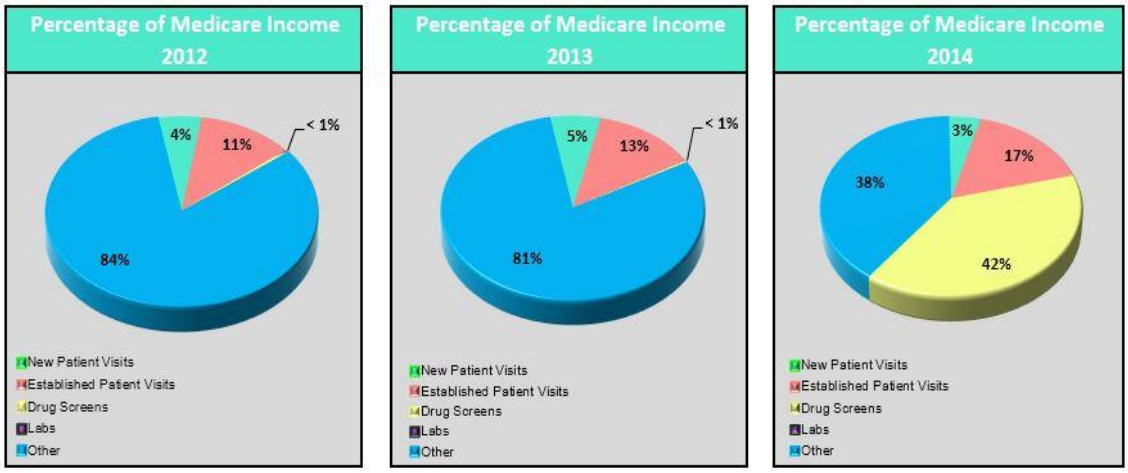
18. After CPS had acquired his practice, Dr. Brummett's utilization of urine drug screens increased significantly to constitute approximately 41% of Medicare payments in 2014, resulting in approximately $188,000 in Medicare reimbursement.

19. Medicare data shows the enormous increase in Dr. Brummett's utilization of urine drug tests before and after the practice was bought by CPS:



20. Similarly, before CPS acquired the Alton, Illinois practice in June 2014, according to Medicare data, urine drug screens ordered by Dr. Buenger constituted approximately 1% of Medicare payments paid to the practice. In 2013, drug screens ordered by Dr. Buenger constituted less than 1% of Medicare payments, resulting in approximately $2,000 of Medicare payments for drug screens performed on 87 patients.

21. After CPS had acquired his practice, Dr. Buenger's utilization of urine drug screens increased significantly and, in 2014, constituted approximately 42% of Medicare payments in 2014, resulting in roughly $264,000 in Medicare reimbursement on hundreds of patients.



22. CPS providers in other locations had similarly sharp increases in the volume of drug screens performed after CPS acquired their practices.

23. Providers who increased their volume of urine drug screen orders after being acquired by CPS included Dr. Suresh Krishnan in Troy, MO; Dr. Timothy Beacham in Greenville, MS; Dr. Ronald B. Williams in Flowood, MS; Dr. Barbara Schooley in Nashville, TN; Dr. William J. Martin in Elkin, NC; Dr. Nancy Faller in Winston Salem, NC; Dr. Todd A. Pepper in Athens, TN; Dr. Jeffrey Hall in Jonesboro and Paragould, AR, and Germantown, TN; Dr. Daniel McHugh in Nashville, Clarksville, and Franklin TN; Dr. Thomas Meloy in Winston Salem, and Kernersville, NC; Dr. Christopher Middendorf in

Lawrenceburg, IN; Dr. Cynthia Neindorff in Knoxville, TN; Dr. John Mattingly in Swansea, IL; Dr. Raymond Greaser in Oxford, MS; Dr. Joey Thomas in Petersburg, VA and Roanoke Rapids, NC; Dr. Michael Danko in Cincinnati, OH, and Dr. Rex Williams in Flowood, MS.

24. Before being acquired by CPS, these providers' Medicare reimbursement received for drug screens was approximately $2,000 in aggregate, with many providers not ordering any testing at all. After acquisition by CPS, providers' reimbursement rose over $2 million dollars between 2013 and 2014.

25. Medicare reimburses providers only for the cost of services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y.

26. Through consistent policies and practices, however, Defendants billed Medicare, Medicaid, and private insurance plans in Illinois for laboratory tests, including drug screens, even when the tests were not reasonable and necessary for the diagnosis or treatment of illness or injury.

27. For example, as set forth herein, CPS ordered expensive and unnecessary qualitative and quantitative drug screens month after month, even for patients who are 80 plus years of age, have no aberrant behavior, and even though CPS had no reasonable belief that those patients require such repetitive and expensive drug screens as part of their treatment.

28. Significantly, CPS required non-clinical staff – medical assistants with little or no formal education – to order repetitive and expensive drug screens for up to 17 drugs even before any professionally-trained medical staff could evaluate whether the patient required drug testing.

29. CPS also required that every patient be tested at minimum every two months. In a number of CPS practices, including the Alton, Illinois clinic, CPS requires Medicare patients to be tested at every office visit regardless of medical necessity.

30. Moreover, even after performing such expensive and repetitive tests, CPS physicians and clinical staff often did not use the testing results in the patient's treatment.

31. CPS also submitted claims to federal, state, and private insurers in Illinois, for expensive and unnecessary pharmacogenetics testing ("PGT") which are not reimbursable because most payors will deem the tests to be investigational in most circumstances.

32. CPS also submitted claims to federal, state, and private insurers in Illinois for unnecessary psychological screening tests ("IPAD" screens) for potential drug abuse and depression.

33. Although psychological screening for pain patients may be medically appropriate, reimbursement for such tests is reasonable and necessary *only* when there is a medical indication attributable to an individualized need of a particular patient.

34. Despite this, CPS's policy was to screen all patients repeatedly with these tests, without regard for whether they were appropriate for each patient.

35. CPS enforced its mandatory testing policies and practices through coercion, threats, and intimidation. For example, staff were shown metrics maintained by CPS corporate managers for use, and billing, of psychological tests by each of its clinics. Office managers and staff, clinical and non-clinical, were threatened with reduction in bonuses if their clinic did not meet revenue goals for testing.

36. CPS's policies and practices to induce and coerce clinical staff to order unnecessary tests violated norms of medical practice.

37. Starting from at least 2013, CPS offered financial incentives to nurse practitioners and physician assistants for each test ordered and billed. CPS circulated

memoranda describing bonuses it would pay to nurse practitioners and physician assistants per test including $10 for each urine drug screen, $25 for each genetic test, and $5-10 for each IPAD psychological test.

38. Such financial bonuses designed to reward the volume and value of referrals for testing, including medically unnecessary testing, violate the Anti-Kickback Statute's prohibition on paying employees remuneration based directly or indirectly on the volume or value of referrals. 42 C.F.R. § 411.357(c)(ii).

39. Through these practices, Defendants submitted and continues to submit false or fraudulent claims for reimbursement of its drug screens, genetic tests, psychological testing, and office visit services, in violation of the federal False Claims Act and the similar statutes of the Plaintiff-States.

40. CPS has also failed to reimburse federal and state health programs under its obligation to repay overpayments. *See* 42 U.S.C. § 1320a-7k(d), 31 U.S.C. § 3729(a)(1)(G).

41. *Qui tam* Plaintiff-Relator Allison Chancellor seeks through this action to recover all available damages, civil penalties, and other relief for the FCA and state law violations alleged in this Complaint as well as incorporates by reference the allegations set forth in the United States and the State of Tennessee's Consolidated Complaint in Intervention filed on July 22, 2019.

III. PARTIES

A. The Relator

42. Plaintiff-Relator Allison Chancellor ("Plaintiff" or "Relator") is an individual residing and domiciled in the State of Missouri. She holds a B.S. in Biology with a concentration in cell and molecular science, and an M.S. in Physician Assistant Studies. She is licensed in Illinois and Rhode Island as a Physician Assistant, and additionally holds a controlled substance license in Illinois. She also is a licensed Pharmacy Technician in

Alabama. In February 2015, Relator began working for CPS as a Physician Assistant in the Alton, Illinois CPS office, where she worked until her termination on June 3, 2015.

43. In her capacity as a Physician Assistant at CPS, Relator had direct knowledge of CPS's testing practices including urine drug screens, PGT, psychological testing, and office visits.

B. Defendants

44. Defendant Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists ("CPS") is a Tennessee professional limited liability company with a principal place of business in Franklin, Tennessee. The principal members of CPS are Defendants Dr. Peter Kroll, Dr. Steven Dickerson, and Dr. Gilberto Carrero. It is co-owned by Drs. Kroll, Dickerson, Carrero, and Dr. Richard Muench. .

45. In July 2018, CPS began dissolution proceedings. When operating, it offered a variety of pain management services to patients. CPS owned clinical laboratories to perform testing of specimens drawn from patients at its clinics.

46. Defendant Carrero is a medical doctor certified in anesthesiology and pain management who resides in Nashville, Tennessee.

47. Defendant Davis is an individual who resides in Franklin, Tennessee, and was the Chief Executive Officer of CPS from May 2011 to June 2017. Davis has no medical training or certification.

48. Defendant Dickerson s a medical doctor certified in anesthesiology and pain management who resides in Nashville, Tennessee.

49. Defendant Kroll s a medical doctor certified in anesthesiology and pain management who resides in Goodlettsville, Tennessee.

50. Defendant Smith is a chiropractor, who resides in Cleveland, Tennessee.

IV. JURISDICTION AND VENUE

51. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

52. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732, which authorizes nationwide service of process. Moreover, Defendants can be found, resides in, or has transacted the business that is the subject matter of this lawsuit in the Middle District of Tennessee.

53. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the Plaintiff-States on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the Constitution.

54. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant can be found, resides in, or has transacted the business that is the subject matter of this lawsuit in the Middle District of Tennessee.

55. The Plaintiff-Relator's complaint is not based upon allegations or transactions of fraud that have been publically disclosed within the meaning of the False Claims Act. Even if the allegations or transactions of fraud had been publicly disclosed, the Plaintiff-Relator is an original source of the information within the meaning of the FCA. Her information is based upon her personal observations, independent of any relevant public disclosure and materially adds to any information that could have been publicly disclosed. To the extent the applicable statutes of the Plaintiff-States contain public disclosure provisions, those provisions also do not bar this suit.

V. APPLICABLE LAW

A. The False Claims Act

56. The federal False Claims Act (the "FCA") was originally enacted during the Civil War. After finding that fraud in federal programs was pervasive and that the FCA, which Congress characterized as the primary tool for combating government fraud, was in need of modernization, Congress substantially amended the FCA in 1986 to enhance the ability of the United States Government to recover losses sustained as a result of fraud against it. Congress intended that the 1986 amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf. Congress further substantially amended the FCA in 2009 and 2010 to, among other things, strengthen whistleblowers' ability to bring and maintain actions on the Government's behalf.

57. The FCA prohibits, *inter alia*: (a) knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; and(b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim. 31 U.S.C. §§ 3729(a)(1)(A), (B), (G). Any person who violates the FCA is liable for a civil penalty of up to $21,563 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. §3729(a)(1).

58. For purposes of the FCA, a person "knows" a claim is false if that person: "(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that the Defendant specifically intended to commit fraud. *Id.* Unless otherwise indicated, whenever

the word "know" and similar words indicating knowledge are used in this Complaint, they mean knowledge as defined in the FCA.

59. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. Such a person is known as a qui tam "relator." The FCA requires that the qui tam relator's complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

B. The Medicare Program

60. Congress established the Medicare program, or Title XVIII of the Social Security Act, in 1965 with the goal of providing nationalized health coverage for Americans aged 65 or older. In addition to the elderly, a large portion of Medicare's patient population is disabled. In 2015, Medicare covered roughly 55 million Americans, either through the traditionally federally administered Medicare program or through a private health plan, also known as a Medicare Advantage plan. Medicare is funded through the Medicare Trust Fund, which relies on workers' payroll deductions and government funds.

61. The United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS, direct and manage the Medicare program.

62. Medicare has four parts: Part A, providing hospital insurance; Part B, providing medical insurance, Part C, which includes managed care plans; and Part D, which provides prescription drug benefits. Medicare Part B includes reimbursement for covered laboratory tests when the tests are medically necessary and reasonable.

63. Section 1862 of the Social Security Act, codified at 41 U.S.C. §1395y(a)(1)(A), explains that under Medicare Part B, "no payment may be made under part

A or part B for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the prevention of illness."

64. In order to administer Part B and provide payment to medical service providers in various geographical areas, the federal government contracts with private companies. These entities are known as Medicare Administrative Contractors or "MACs." MACs are tasked with processing Medicare claims, determining coverage for patients, and reimbursing providers from the Medicare Trust fund. 42 U.S.C. § 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104.

65. CPS billed Medicare under Part B, which covers medical services furnished by physicians and other providers and suppliers, including clinical laboratory testing services. 42 U.S.C. § 1395k(a)(2)(B).

66. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

C. <u>The Medicaid Program</u>

67. Medicaid is a public-assistance program created in 1965 that provides payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the federal government and those states participating in the program. Medicaid is the largest source of funding for medical services for America's poor and disabled. Each provider that participates in the Medicaid program must sign a provider agreement with his or her state.

68. Federal regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX of the Social Security Act and with the regulations the Secretary of HHS promulgates. Although Medicaid is administered on a

state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the items and services for which the federal government will pay through its funding of state Medicaid programs.

69. Like Medicare, Medicaid covers laboratory testing and medical services only if it is necessary to diagnose or treat a patient's particular medical condition. Medicaid routinely pays for testing and services if they meet those standards. Although Medicaid reimbursement for laboratory testing varies depending on the state in which the billing is done, all services provided must meet the medical necessity threshold.

70. Physicians and laboratories receiving reimbursement from Medicaid must make express and/or implied certifications in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid.

D. Other Federal and State-Funded Health Care Programs

71. The federal Government administers other health care programs that include, but are not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program. All of these programs reimburse for laboratory testing and medical services when they are reasonable and medically necessary.

72. TRICARE, which the United States Department of Defense administers, is a health care program for individuals and dependents affiliated with the armed forces. 10 U.S.C. § 1071, *et seq.*; 32 C.F.R. § 199.4(a).

73. CHAMPVA, which the United States Department of Veteran Affairs Administers, is a health care program for families of veterans with 100-percent service-connected disabilities. 38 U.S.C. § 1781, *et. seq.*; 38 C.F.R. § 17.270(a).

74. The Federal Employee Health Benefit Program, which the United States Office of Personnel Management administers, provides health insurance for federal employees, retirees, and their survivors. 5 U.S.C. § 8901, *et seq.*; 5 C.F.R. § 890.12.

75. The States have programs providing health care benefits to certain individuals based on those individuals' financial need, employment status, and other factors. This complaint refers to those programs as "state-funded health care programs."

E. The Illinois Insurance Claims Fraud Prevention Act

76. The Illinois Insurance Claims Fraud Prevention Act, 740 ILCS 92/1 *et seq.*, IFPA) allows whistleblowers to bring *qui tam* cases against private insurance companies that submit false or fraudulent claims to private insurance companies.

77. Violations of the Act, or of Article 46 of the Illinois Criminal Code of 1961, which makes it an offense to knowingly obtain, attempt to obtain, or cause to be obtained by deception, control over the property of an insurance company, are subject to penalties of not more than $10,000 and not more than three times the amount of each claim.

78. Claims presented to private health insurers doing business in Illinois for services that are not reimbursable because the services are not medically necessary, violate the IFPA.

79. The IFPA functions much like the federal False Claims Act in that cases are filed under seal with 60 days provided for the government to investigate the allegations. Actions by private individuals for violations of the Act are brought in the name of the State. 740 Ill. Comp. Stat. § 92/15(a).

80. If the State proceeds with the action brought by a whistleblower under the Act, the statute provides that the whistleblower will receive not less than 30% of the proceeds of the action or settlement of the claim. 740 Ill. Comp. Stat. § 92/25(a). If the State does not intervene in the action, the whistleblower will receive an amount not less than 40% of the proceeds or settlement of the action.

E. Regulations Regarding Coverage for Laboratory Tests

81. Medicare, Medicaid, and other federal and state health program regulations require that laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury. Laboratory test orders that are not individualized to patient need (or for which the patient need is not documented in the patient chart) are not covered services, and claims for such services must be denied.

a. Medicare Coverage for Laboratory Tests

82. Medicare Part B only covers services, including diagnostic laboratory services, that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

83. Pursuant to 42 C.F.R. 410.32(a), all diagnostic tests must be ordered by the physician who is treating the beneficiary, that it, the physician who furnishes a consultation or treats a beneficiary for *a specific medical problem* and who *uses the results in the management of the beneficiary's specific medical problem*." 42 C.F.R. § 410.32(a) (emphasis added). The physician must clearly document in the medical record his or her intent that the test be performed. *See* Medicare Benefit Policy Manual ("MBPM"), Ch. 15, Section 80.6.1.

84. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. 410.32(a). Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. 410.32(a). MBPM, Ch. 15, Section 80.1.

85. Medicare requires proper and complete documentation of the services rendered to beneficiaries. 42 U.S.C. 1395l(e).

86. Medicare regulations state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. 410.32(d)(3).

87. The Department of Health and Human Service's Office of Inspector General has published Compliance Program Guidance for Clinical Laboratories advises that

> "[u]pon request, a laboratory should be able to produce or obtain from the treating physician (test ordering), authorized person on the physician's staff or other individual authorized by law to order tests the documentation to support the medical necessity of the service the laboratory has provided and billed to a Federal or private health care program." 63 Fed. Reg. 45076, 45079 (Aug. 24, 1998).

88. OIG Compliance Guidance states that "laboratories should encourage physicians or other authorized individuals to submit diagnosis information for all tests ordered, as documentation of the medical necessity of the service" and that "Medicare generally does not cover routine screening tests." *Id.*

89. The Medicare National Coverage Determinations Coding Policy Manual and Change Report currently states that "[s]ervices that are excluded from coverage include routine physical examinations and other services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of 'screening' services, *including laboratory test services furnished in the absence of signs, symptoms, or personal history of disease or injury*, except as explicitly authorized by statute." CMS, The Medicare National Coverage Determinations Coding Policy Manual and Change Report, 2 (Oct. 2015) (emphasis added) *available at* https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/Downloads/manual201510_ICD10.pdf.

90. Significantly, OIG's Guidance explains that medical necessity will not be met generally for "routine screening tests," only tests that are "covered, reasonable, and necessary for the beneficiary, given his or her clinical condition." *Id*.

91. As a condition of Medicare payment, a physician or other Medicare-qualified clinical personnel (such as physician assistants and nurse practitioners) must certify that the testing performed is medically necessary and reasonable for the diagnosis and treatment of the patient. 42 U.S.C. § 1395n(a)(2)(B); 42 C.F.R. § 424.10(a).

92. In some instances, recertification of the necessity of the services is also required by the physician. 42 C.F.R. § 424.10(a). The physician, nurse practitioner, clinical nurse specialist, or physician signing the certification must have knowledge of the case. 42 C.F.R. § 424.24(g)(2).

93. A claim is properly denied where the service provided is not reasonable and necessary and the necessity is not documented in the medical record, or if the MAC has made a local coverage determination that the service is not covered. 42 C.F.R. § 410.32(d)(2)(i)-(iii); (d)(3)(ii)-(iii).

b. Medicaid Coverage for Laboratory Tests

94. Like Medicare, other federal and state health insurance programs cover laboratory testing and medical services only if it is necessary to diagnose or treat a patient's particular medical condition.

95. For example, the Illinois Department of Healthcare and Family Services (the agency which manages Illinois' Medicaid Program) Handbook for Providers of Laboratory Services, Chapter L-200, Policy and Procedures for Laboratory Services (May 2016) States that "Non-Covered Services *for which medical necessity is not clearly established are not covered by the Department's Medical Programs* . . . In addition, the following laboratory

services are excluded from coverage in the Department's Medical Programs and payment will not be made for the provision of these services:

• Laboratory services *when not specifically required by the condition for which the patient is being treated such as blanket "rule out" or open-ended tests*

• Laboratory services provided to patients eligible for Medicare Part B benefits when the *Medicare intermediary determines that the services are not medically necessary*

c. Private Insurance Policy Coverage for Laboratory Tests

96. Private insurers typically use similar policies as the federal government as to what is medically necessary.

97. BlueCross BlueShield of Illinois, a private insurer covering patients in Illinois, published Medical Policy MED207.154, Urine Drug Testing Including Pain Management and Substance Abuse Monitoring on November 1, 2015. This policy states that "drugs or drug classes for which screening is performed should only reflect those likely to be present based on the patient's medical history or current clinical presentation, and without duplication. Each drug or drug class being tested for, must be indicated by the referring clinician in a written order and so reflected in the patient's medical record."

98. The BlueCross BlueShield of Illinois policy further states that qualitative drug screening may be considered medically necessary for baseline screening when there is a clinical assessment of patient history and risks of abuse, the clinicians have knowledge of test interpretation, and a plan to use the results clinically.

99. Quantitative screening is medically necessary when immunoassays for the drugs are not available, or when documented and present qualitative results are positive for a prescription drug that is not prescribed to the patient, negative for a prescription drug prescribed to a patient, or positive for an illicit drug *and* the quantitative drug levels are required for clinical decision making.

100. The policy specifically notes that "Confirmatory testing is not appropriate for every specimen and should not be done routinely. This type of test should be performed in a setting of unexpected results and not on all specimens. The rationale for each confirmatory test must be supported by the ordering clinician's documentation."

101. Finally, the policy emphasizes that "Routine screenings, including quantitative panels, performed as part of a clinician's protocol for treatment, **are not considered medically necessary."** (emphasis in original).

102. Prior coverage policies are similar in requirements to current policies and implement relevant federal and states statutes and policy requirements.

F. The Anti-Kickback Statute

103. The federal health care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), arose out of Congressional concern that financial inducements can influence health care decisions and result in goods and services being more expensive, medically unnecessary, and harmful to patients.

104. To protect the integrity of federal health care programs, Congress prohibited the payment of kickbacks in any form, regardless of whether the kickback actually gives rise to overutilization or unnecessary care. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare and Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

105. The AKS prohibits any person or entity from making or accepting payments to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b).

106. The statute prohibits laboratories from offering or paying any remuneration, in cash or kind, directly or indirectly, to induce or influence physicians or others to order or recommend laboratory services that may be paid for by federal health care programs. The AKS has been interpreted to cover any arrangement where *one* purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.

107. The AKS also prohibits employers to pay their employees bonuses based directly or indirectly on the volume or value of referrals. 42 C.F.R. § 411.357(c)(ii).

108. Compliance with the AKS is a precondition to both participation as a health care provider in and payment under Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. 42 U.S.C. § 1320a-7(b)(7).

109. For example, to establish eligibility and seek reimbursement from the Medicare Program, hospitals and other providers enter into Provider Agreements with CMS. As part of that agreement, the provider must sign the following certificate:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

110. Similarly, compliance with the federal AKS is a prerequisite to a provider's right to receive or retain reimbursement payments from government-funded health care programs.

111. In sum, physicians, hospitals, and other providers who participate in federal health care programs must certify (often explicitly, in a provider agreement or on claim

forms) that they have complied with the applicable federal rules and regulations, including the AKS.

112. Any party convicted under the AKS must be excluded from federal health care programs (*i.e.*, not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1).

113. Even without a conviction, if the Secretary of the Department of Health and Human Services ("HHS") finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

114. Pursuant to the Affordable Care Act passed in 2010, any claim submitted to a federal health care program that includes items or services resulting from violations of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. 42 U.S.C. § 1320a-7b(g).

115. The States also have enacted statutes prohibiting kickbacks in connection with State Medicaid services. Pursuant to State statutes, regulations, and other administrative materials, the States have made compliance with both federal and State anti-kickback statutes and rules a prerequisite to receiving or retaining reimbursement payments from state-funded health care programs. *See* 305 Ill. Comp. Stat. 5/8A-3(b)(2), (c)(2); Ind. Code § 12-15-24-2; N.C. Gen. Stat. §§ 108A-63(g), (h), 108A-70.16, N.C. Admin. Code 22F.0301(5); Tenn. Code Ann. § 71-5-118; Tenn. Comp. R. & Regs. §§ 1200-13-1-.05(1)(a)(6), 1200-13-1-.21(2), (3); Va. Code Ann. §§ 32.1-315; *see also* Illinois Medicaid Handbook; and the Virginia Medicaid Provider Manual.

116. Many states, including the Plaintiff-States, also require Medicaid providers, including laboratories, to enter into provider agreements requiring them to comply with all applicable federal and State Medicaid Laws (sometimes with specific emphasis on the AKS) and/or conditioning the right to payment on compliance with those laws.

VI. ALLEGATIONS

A. Medicare and other Federal and State Health Programs Do Not Reimburse Laboratory Testing Unless Medically Necessary

117. Drug testing is often an appropriate clinical tool in the medical management of pain patients. By performing drug tests, medical practitioners can verify whether pain patients are compliant with taking the drugs they have been prescribed, and whether the patient may be taking other drugs, including illicit ones, that could interfere with treatment or pose addiction dangers.

118. For this reason, for many pain patients, including those with chronic pain, receive drug tests at appropriate intervals, when the physician or other properly licensed medical provider deems the tests medically necessary for management of the patient and an appropriate part of that patient's care.

119. Under those circumstances, drug tests may appropriately be reimbursed by insurers including Medicare, Medicaid, and private insurers in Illinois.

120. Typically, when medical providers order drug tests, they will first order a qualitative test to detect the presence or absence of drugs or metabolites (often known as "analytes") in the sample.

121. Urine is the most common medium used for drug testing, and is the most common method used by CPS.

122. A typical qualitative drug test panel includes testing for the presence of cocaine, opiates, opioids, heroin, amphetamines, methamphetamine, benzodiazepines,

phencyclidine (PCP), MDMA, barbiturates, methadone, tricyclic antidepressants, synthetic or "designer" drugs, oxycodone, and the active ingredient of marijuana, THC.

123. Qualitative testing does not measure the concentration of drugs in the sample.

124. Depending on the initial results from qualitative testing, it may be medically appropriate to perform a quantitative drug test subsequently to test separately for the concentration of specific drugs in a patient's system.

125. The purpose of quantitative testing is to confirm any positive results from the qualitative test and to determine the concentration of the drug present.

126. Unlike the qualitative test, which can test for all drugs in the sample at once, quantitative testing requires that a separate test be run for each different drug.

127. Because each drug tested for requires a separate test, the testing equipment needed is much more sophisticated than needed at the qualitative level. quantitative testing is more expensive to perform.

128. Accordingly, by performing drug tests in two steps, and running quantitative testing for only those drugs that a patient tests positive for on the qualitative test, the overall cost of drug tests for the payor can be lowered significantly and can be done more efficiently in terms of both cost and patient care.

129. Most patients will not test positive for any drugs on a screening test (save those being prescribed to them) and, if there are positive results, those are typically limited to no more than a few drugs.

130. Therefore, even those patients with positive results do not need quantitative testing for all of the same drugs that the quantitative screening test detects.

131. Medicare rules on drug tests reflect the need to limit drug tests to those patients for whom the test is needed for their medical management and care as evaluated by medical practitioners.

132. Medicare rules also limit quantitative screening, in most cases, to clinical situations where qualitative screening has been performed and the results of that test indicate that quantitative tests for particular drugs are needed.

133. For example, a MAC National Government Services, Inc., Local Coverage Determination (LCD) covering Illinois, directed that qualitative screening is medically necessary and reasonable, and therefore reimbursable by Medicare, in patients who are at high risk of medication or substance abuse or have demonstrated they will likely be non-compliant with a drug regime. And, "[d]rugs or drug classes for which screening is performed should reflect only those likely to be present, based on the patient's medical history or current clinical presentation." Qualitative Drug Screening (L28145), National Government Services, Inc. (July 18, 2008) (retired LCD that covered Illinois).

134. Similarly, a current LCD issued by MAC Palmetto GBA requires that medical necessity be indicated by specific patient need, stating that "[c]riteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements: Patient history, physical examination and previous laboratory findings; Current treatment plan; Prescribed medication(s); [and] Risk assessment plan." Controlled Substance Monitoring and Drugs of Abuse Testing (L35724), Palmetto GBA (Oct. 1, 2015) (covering South Carolina and Virginia).

135. A similar LCD notes that testing all patients at a pain clinic, without regard to their individualized medical history or presentation, is not medically necessary. Controlled Substance Monitoring and Drugs of Abuse Testing (L35006), Novitas Solutions, Inc. (Oct. 1, 2015) (covering Louisiana, Arkansas, and Mississippi).

136. The frequency of qualitative drug testing also must be individualized to patient need in order to be reasonable and medically necessary.

137. Ongoing testing in chronic opioid therapy patients can be acceptable, as can randomized testing, but only under specific conditions particular to the individual patient.

138. For example, where the frequency of testing is

> [B]ased on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern. The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications.

Controlled Substance Monitoring and Drugs of Abuse Testing (L35724), Palmetto GBA, (Oct. 1, 2015) (covering South Carolina and Virginia).

139. So too, quantitative testing "may be reasonable and necessary *based on patient specific indications*, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions." Controlled Substance Monitoring and Drugs of Abuse Testing (L35006), Novitas Solutions Inc. (Oct. 1, 2015) (covering Louisiana, Arkansas, and Mississippi). These circumstances occur when: "1. The results of the qualitative screen are presumptively positive; or 2. Results of the screen are negative and this negative finding is inconsistent with the patient's medical history." Pathology and Laboratory: Qualitative Drug Testing (L34501), Cahaba Government Benefit Administrators, LLC (Oct. 1, 2015) (covering Alabama and Tennessee).

140. However, Medicare carriers note that routine and indiscriminate quantitative testing of all pain patients is not medically necessary because "the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice." Controlled Substance Monitoring and Drugs of Abuse Testing (L35724), Palmetto GBA (Oct. 1, 2015) (covering South Carolina and Virginia). "

141. For these reasons, Medicare rules require that drug screens be individualized based on clinical history and risk assessment, and be documented in the medical record." *Id*. There should be specific documentation in the medical record to support why quantitative testing is medically necessary.

142. Although "baseline" qualitative testing of patients on pain management regimes can be acceptable in certain circumstances, "[f]requency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record." Controlled Substance Monitoring and Drugs of Abuse Testing (L35724), Palmetto GBA (Oct. 1, 2015) (covering South Carolina and Virginia).

143. Medicare LCDs also address with what frequency drug tests are medically necessary based on a risk assessment for the patient.

144. For example, in addition to an initial baseline testing before beginning chronic opioid therapy, there is a range of frequencies that may be appropriate based on what medications the patient is using and the risk that they may be using illicit drugs, 1-2 timesevery 12 months in low risk patients; 1-2 times every 6 months in moderate risk patients; and 1-3 times every 3 months in high risk patients.

145. Any testing beyond the guidelines "must be justified by the clinician in the medical record in situations in which changes in prescribed medications may be needed." Controlled Substance Monitoring and Drugs of Abuse Testing (L35724), Palmetto GBA (Oct. 1, 2015) (covering South Carolina and Virginia); Controlled Substance Monitoring and Drugs of Abuse Testing (L36029), CGS Administrators, LLC (Oct. 1, 2015) (covering Ohio and Kentucky); Urine Drug Testing (L36037), National Government Services, Inc. (Dec. 1, 2015) (covering Illinois).

B. <u>CPS's Aggressive Urine Drug Screen Policies and Practices Removed Judgment from Medical Decision-making and Resulted in High Volumes of</u>

Unnecessary Tests and Submission of False or Fraudulent Claims for Reimbursement

146. Despite Medicare's rules, CPS's routine practice was to require untrained staff, including medical assistants, to order unnecessary, repetitive, and indiscriminate urine drug screens for its patients, often not reviewed by medical staff or a physician before ordered, and to submit claims for reimbursement for those tests to federal, state, and private insurers in Illinois.

147. When Relator began working at CPS, she received training from the CPS staff in the Alton, Illinois clinic and received CPS's eCW manual for its work flow policies and procedures.

148. CPS's eClinicalWorks ("eCW") training manual set forth a template for "Ordering Urine Drug Screens (UDS)" which provided that all patients would have ordered both qualitative and quantitative drug screens.

149. Relator learned that CPS required that its staff order urine drug screens for established patients at minimum every two months whether or not there was an individualized need for their medical management.

150. Patients are not allowed to obtain a prescription until they have given a specimen for urine drug screening at their visit.

151. Only *after* providing the sample will the patient be seen by a medical provider (for established patients, usually a physician assistant or a nurse practitioner, or for new patients, a physician).

152. Non-clinical CPS staff ordered urine drug screens by selecting one of several types of drug testing panel options in CPS's electronic health records (eCW) system. The panels are differentiated by Medicare or non-Medicare and "Long Term Use" or "Medication Monitoring."

153. Once the selection for the drug screen is made, it was Relator's understanding that CPS referred an order for both qualitative and quantitative urine drug screens at the same time to its laboratories.

154. Quantitative testing was ordered from the first order even if results from the qualitative tests had been obtained first, and the drug screen was negative, the quantitative drug screen could have been avoided entirely.

155. Significantly, despite this intensive policy for screening all patients, CPS also often did not use the results of urine drug screens in the medical management and care of its patients. At times, the failure to review the urine drug screens can put some patients at risk.

156. Urine drug screen test results were available to view in the eCW system within 5-7 days.

157. However, in many cases, CPS staff did not review the patients' urine drug screen results and did not use them in medical management of the patient, or would review them at such a later date from the test that the results were of questionable use—sometimes over two months after the tests were performed.

158. Even though the results of the previous urine drug screens had not been used in the medical management and care of the patient, CPS staff would continue to order full urine drug screen tests—both qualitative and quantitative for all drugs—at each patient visit.

159. CPS required its staff to order urine drug screens with frequency greater than that allowed by Medicare conditions of reimbursement.

160. Many CPS patients had urine drug screens as frequently as every two months even without any determination by a medical provider that the patient's risk profile warranted repetitive testing.

161. Relator was instructed that, for Medicare patients, urine drug screens should be ordered every time a patient had an office visit. Relator was told by CPS staff that

Medicare patients were less likely to question the urine drug screens because they were unlikely to review the claims submitted to Medicare.

162. On December 9, 2015, the CPS Education & Compliance Team revised its policy about urine drug screens and instructed its providers and staff that "the number of two-month cycle appointments should be limited to very specific and well documented reasons and should not be more than 25% of overall visits." This change in policies was expected to result in even more frequent screening for patients who came in to the CPS clinic monthly to pick up their prescription.

163. CPS's policies for frequent drug screens were inconsistent with Medicare coverage policies concerning the medical necessity for frequent urine drug screens.

164. For example, Medicare LCDs categorize patients by risk and recommend that testing should not be more frequent than 1-2 times every 12 months for low risk patients, 1-2 times every 6 months for moderate risk patients, and 1-3 times every 3 months for high risk patients. *See*, *e.g.*, Controlled Substance Monitoring and Drugs of Abuse Testing (L35724), Palmetto GBA, Original Effective Date Oct. 1, 2015 (covering South Carolina and Virginia).

165. Under CPS's policies and practices, at least 75% of CPS patients were tested with a frequency that Medicare might consider medically appropriate only for high risk patients on chronic opioid therapy.

166. CPS's patient population did not consist of 75% high risk patients and, in fact, CPS had patients that were not on chronic opioid therapy at all.

167. CPS's policy of frequently ordering and performing both qualitative and quantitative drug tests simultaneously was not based on medical necessity but rather on the corporate expectations of achieving revenue targets through laboratory income and frequent office visits.

168. Even patients of advanced age, with no known drug history, were tested repeatedly even though there is no need for these tests as part of their clinical care.

169. Claims for these patients were submitted to Medicare Part B of Illinois Government Services, Coventry MO Illinois, MXR HMO, United HealthCare Medicare Advantage, and other Medicare plans.

170. During her period of employment, Relator identified over 80 patients who received urine drug screens that were not medically necessary.

171. Examples of patients who received unnecessary tests for which false and fraudulent claims were submitted include one patient insured by Medicare Part B of Illinois Government Services. The 88-year old man had no aberrant drug-related behavior and visited CPS's Alton, Illinois clinic for shoulder injections. Nonetheless, frequent and unnecessary urine drug screens were ordered for him even though he was not prescribed any prescription medication by CPS.

172. Another example of a false and fraudulent claim was for unnecessary urine drug screens performed on a 67-year old woman insured by Medicare Part B of Illinois Government Services. At CPS's Alton clinic, this woman patient received six drug urine drug screens within a ten-month period despite never receiving any non-compliant test results. CPS staff did not timely review her test results and in one case took 139 days to review the results of one of her urine drug screens, a period that would not allow them to use the test for any medical management of the patient.

173. Another example of false and fraudulent claims was for urine drug screens that were performed for sound medical reasons but were not used in the patient's medical management. These urine drug screens were performed on a 66-year-old male Medicare patient, seen by a Physician Assistant at CPS's Alton, IL clinic. This patient's urine drug

screen returned positive results for Buprenorphine and Norbuprenorphine, but this patient's chart inaccurately indicated that his urine drug screen results were compliant.

174. Four weeks later this male patient tested positive again for NorHydrocodone, but at his following appointment there was no indication that his urine drug screen results had been reviewed and recognized as non-compliant. Three additional urine drug screens were performed over the next five months, all of which showed positive results for illicit drugs. Nonetheless, nowhere in the medical record does it demonstrate that these tests results were used by CPS or that any steps were taken to control the patient's use of pain medication. In addition, simultaneous qualitative and quantitative testing was performed for these urine drug screens. Claims for all of these urine drug screens were submitted to Medicare even though the results were ignored by CPS staff and not used in the patient's medical management or care.

175. In sum, many CPS patients were given both qualitative and quantitative tests at the same time even though there was no reason to think that they would test positive on the qualitative test for the drugs that were to be measured through the quantitative tests.

176. Many CPS patients were tested even though the results of the urine drug screens were not used or reviewed in conjunction with any clinical plan.

177. Conversely, often providers and clinical staff also did not review or use the results of urine drug screens even for CPS patients for whom performing a urine drug screen was reasonable and necessary, and who tested positive for licit and illicit drugs. Such practices posed significant risk of patient harm.

178. CPT codes typically used for the UDT laboratory tests that CPS performs are: 82145 (Amphetamine or methamphetamine level); 83925 (Opiates measurement); 82520 (Cocaine level); 82649 (Dihydromorphinone level); 83789 (Mass spectrometry using the laboratory testing method); 84311 (Chemical analysis using spectrophotometry);

82055(Alcohol level); 80154 (Benzodiazepines level); 83805 (Meprobamate [sedative] level); 83992 (PCP drug level); 82646 (Dihydrocodeinone drug level); 83840 (Methadone level); 80299 (quantitation of drug); 82542 (chemical analysis using chromatography technique); 82570 (creatinine level to test for kidney function or muscle injury); 83986 (body fluid ph level); G0431 (drug screen, qualitative: multidrug classes by high complexity test method per patient encounter); and 81003 (automated urinalysis test).

179. The average Medicare payment per service for these CPT codes ranges from $4.74 to $26.90. When drug screens for multiple drugs are performed, the average payment per patient from Medicare is approximately $300.

180. Defendants knew that many of these claims were materially false and, in conducting indiscriminate, repetitive urine drug screens, unnecessary quantitative testing, and submitting claims for reimbursement for these tests to federal, state and private insurers, acted recklessly and in deliberate indifference to material conditions of reimbursement.

181. False and fraudulent claims were submitted to federal and state governmental and private plans in Illinois and Defendants received payment for these false and fraudulent claims.

C. Pharmacogenetic (Genetic) Testing is Investigational and Not Medically Necessary or Reasonable, Yet CPS Billed Medicare and Medicaid for These Services

182. CPS policies for laboratory tests for patients extended beyond urine drug screens to performing pharmacogenetics (PGT) testing on patients.

183. PGT looks for variations in genes that influence how fast a patient might metabolize pharmaceutical drugs. The clinical value of that information is very limited. There are many other factors aside from genetics that can influence patients' reactions to drugs, and most drugs are widely used safely and effectively without genotyping. Genetic variations that suggest patients may have more of a chance of adverse events upon taking a

drug are also of limited value because in general, the risk of adverse, severe events is extremely low. Furthermore, there is little credible and useful information on how to correlate genetic variations with actual dosage increases or decreases or other actionable clinical decisions.

184. Because of those reasons, most PGT offer little in the way of useful information that can be translated to clinically significant benefits for patients. This is why most uses of PGT are non-reimbursable by Medicare and private payors.

185. CPS was aware that, because reimbursement for PGT is billed using just a few generic CPT codes corresponding with genetic testing, Medicare has no way of differentiating based on the CPT code alone whether the test was medically necessary or not.

186. Perceiving this financial opportunity to boost revenues through unnecessary testing, CPS directed their clinical staff to perform PGT on patients.

187. CPS's panel for PGT testing had three genetic variations that would be eligible for Medicare coverage and reimbursement: 1. testing the VKORC1 and CYP2C9 genes for patients about to begin taking Warfarin (a blood thinner) when enrolled in a clinical study of Warfarin usage; 2. testing the gene CYP2D6 for patients prior to them beginning antidepressant therapy with nortriptyline or amitriptyline; and 3. testing the CYP2C19 gene for patients beginning Plavix, a blood thinner.

188. All other genetic tests on CPS's PGT panel were non-reimbursable by Medicare. *See* Addendum A.

189. None of the PGT that CPS routinely ordered were covered by Medicare for pain management purposes or related medical care.

190. CPS providers and clinical staff used several different CPT codes to bill Medicare for their PGT services to obtain reimbursement.

191. CPS used the non-specific procedure CPT code 81401, Molecular pathology procedure level 2, to bill for certain PGT tests. The average Medicare allowed amount for this CPT code varies, but typically is approximately $150.

192. CPS also billed for PGT tests using CPT code 81226, Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) common variants. This was used for those genes within the CYP2D6 family. Medicare reimburses approximately $320 per test for this CPT code.

193. CPS also used CPT code 81227, Gene analysis (cytochrome P450, family 2, subfamily C, polypeptide 9) common variants, to bill for certain PGT tests. Medicare reimbursed approximately $175 per test for this CPT code. This CPT code can be used to bill tests for a number of different genes.

194. CPS also used CPT code 81355, Gene analysis (Vitamin K epoxide reductase complex (1) variant) to bill for certain PGT. Medicare reimburses approximately $88.20 for this CPT code.

195. CPS also used CPT code 81225, Gene analysis (cytochrome P450, family 2, subfamily C, polypeptide 19) common variants, to bill for certain PGT tests. Like CPT code 81227, this CPT code may be used to cover various PGT tests for different genes.

196. Medicare reimburses approximately $291 for this CPT code.

197. PGT testing is typically billed as a panel that includes tests for multiple gene variations at once. A panel of PGT testing for a single patient can run over $3,000 in Medicare reimbursement.

198. Since at least 2013, Defendants received reimbursement from Medicare for PGT testing using the above CPT codes for those genes listed on their PGT panel.

199. In 2014, for example, Defendants received almost a million dollars of Medicare reimbursement from PGT.

200. In addition to billing government and private insurers for PGT testing that is medically unnecessary, Defendants offered kickbacks in the form of cash bonuses to nurse practitioners and physician assistants for ordering PGT testing.

201. In mid-2015, for example, Defendants offered medical providers and clinical staff a $25.00 bonus for each PGT ordered.

202. Defendants pressured medical providers and clinical staff to order PGT testing by tying these providers' bonus compensation to the volume of testing ordered.

203. Defendants' policy threatened medical providers and staff that their bonuses would not be paid out if the volume of testing was not high enough.

204. In a June 2015 email explaining the new bonus structure for nurse practitioners and physician assistants, CPS's policy stated that "In the event [an NP/PA] has not been participating in all CPS offered services (Genetics, Pain Creams, iPad Tests, Ultrasounds, EMG, etc.) to the satisfaction of the oversight physician and relative to an industry standard, the total bonus amount can be adjusted to lower the total due. . . . In theevent there is a deficit at the quarterly mark, that amount will be deducted from the next month's bonus check. There should not be any reason for a deficit to appear."

205. Although Defendants pushed clinical staff to order PGT testing, CPS providers often do not even use the test results in their patient care, and/or fail to properly document the clinical use of PGT results.

206. For example, "genetic testing" was ordered for chronic pain syndrome for a Medicare patient on December 23, 2014. Under "follow up," the provider noted that this patient would come in for a follow up appointment four weeks later for genetic testing results. On January 20, 2015, the patient returned for his follow up appointment. The only notes related to genetic testing indicate that "Pt presents today for medication refill and follow up of genetic testing." There is no indication in the progress notes of what the results

of the genetic testing were for this patient, which genes were tested for and why, or how they may impact his medical management or care.

207. Even with proper documentation, Medicare and other government and private payors deem PGT as non-covered for most genetic variations.

208. Defendants have knowingly caused the submission of false or fraudulent claims for PGT.

D. Defendants Knowingly Performed Medically Unnecessary and Indiscriminate Psychological Testing and Presented False or Fraudulent Claims for Unnecessary Psychological Testing to Government and Private Insurers

209. Defendants performed medically unnecessary psychological testing and presents claims for these tests to federal and state insurers as well as private insurers in Illinois.

210. CPS's policy was to screen all patients for depression and other mental health issues regardless of whether the patients' previous or current medical history indicates that psychological screening should be performed. This included, for example, patients who sought help with pain management for injuries or other issues where there is no evidence of a predilection toward depression or substance abuse.

211. The sole reason CPS conducted routine and indiscriminate psychological testing is to increase its revenues from federal, state, and private payors in Illinois.

212. By repeatedly performing psychological testing on its patients, CPS repeatedly billed Medicare and other government and private insurers for unnecessary psychological tests.

213. Psychological testing is reimbursable only where medical necessity specific to the patient is documented. Indiscriminate testing of all patients is unlikely to meet medical necessity requirements.

214. The current LCDs that address CPT code 96103, used by CPS to bill for the testing, describe the conditions under which psychological testing is medically necessary:

> The *medical record must indicate the presence of mental illness or signs of mental illness for which psychological testing is indicated* as an aid in the diagnosis and therapeutic planning. The record must show the tests performed, scoring and interpretation, as well as the time involved. . .. *Use of such tests when mental illness is not suspected would be a screening procedure not covered by Medicare.* Each test performed must be medically necessary. *Therefore, standardized batteries of tests are not acceptable unless each test in the battery is medically necessary.*
> Changes in mental illness may require psychological testing to determine new diagnoses or the need for changes in therapeutic measures. *Repeat testing not required for diagnosis or continued treatment would be considered medically unnecessary. Nonspecific behaviors that do not indicate the presence of, or change in, a mental illness would not be an acceptable indication for testing.* Psychological or psychological evaluations that can be accomplished through the clinical interview alone (e.g., response to medication) would not require psychological testing, and such testing might be considered as medically unnecessary.

Outpatient Psychiatry and Psychology Services (L34353), CGS Administrators, LLC (Oct. 1, 2015) (emphasis added); *see also* Psychiatry and Psychology Services (L33632), National Government Services, Inc. (Oct. 1, 2015); Psychological and Neuropsychological Testing (L34646), Wisconsin Physicians Service Insurance Corp. (Oct. 1, 2015)*;* Psychological and Neuropsychological Tests (L34520), First Coast Service Options, Inc. (Oct. 1, 2015).

215. Despite these clear limitations on billing for psychological testing performed as routine screening, CPS policy was to test all new patients "to obtain a base line," regardless of whether patients present with a low or high risk for drug abuse and depression or other mental illnesses, or had changes in their behavior or mental states.

216. CPS incentivized and pressured providers and clinical staff to order repeat "IPAD tests" consisting of two different tests: the Pain Medication Questionnaire-Revised

(referred to as the PMQ-R test) test and the Center for Epidemiologic Studies Depression Scale Revised (referred to as the CCESD-R test) test.

217. The IPad application that CPS used to administer the PMQ-R test was created by a company called Vendition Partners, LLC, located in Canton, GA.

218. Vendition states that the PMQ-R test is "a self-administered assessment tool designed to reflect and identify suspected behavioral and attitudinal correlates of opioid misuse" and that "[t[he PMQ-R is appropriate for initial patient assessment when considering the patient for Opioid therapy and for the ongoing monitoring of patients on oral medication management" and it "flags the potential for medication misuse."

219. Vendition recommends that the PMQ-R be administered even though "strong evidence is lacking on the best methods for managing high-risk patients, potential risks can be minimized by more frequent and intense monitoring compared to lower risk patients." The PMQ-R classifies patients into risk groupings (high, average, or low) according to the likelihood of aberrant drug use.

220. The CCESD-R test that CPS administered is also on an iPad application run by Vendition Partners. It is a self-administered assessment tool designated to reflect the nine categorical symptoms of depression and depressive disorder as defined by the American Psychological Association' Diagnostic and Statistical Manual (DSM-IV). The CCESD-R is appropriate for use in chronic pain for identifying and periodically monitoring underlying comorbid psychological conditions. The CCES-R is also appropriate and useful as an adjunct tool for prevention of misuse of opioid therapy.

221. The tests created by Vendition Partners are of questionable clinical validity.

222. Nonetheless, Vendition Partners promotes repeated testing of patients quarterly stating that "Given the extensive literature that supports psychopathology,

particularly depression and anxiety, as predictive of abuse, psychological comorbidity should be assessed prior to initiating opioid therapy."

223. Vendition Partners recommends retesting pain patients quarterly if they show no signs of clinical significance, monthly if they meet the subthreshold for depression, and at each visit (but no more frequently than every two weeks) if the score indicates a possible major depressive episode or worse.

224. Each new CPS patient was given a PMQ-R on their first visit. CPS medical assistants note that results have been reviewed even though the medical assistants do not typically review the results of the test or know how to interpret them even if done.

225. Results from the PMQ-R were placed in the patient's progress notes. However, no alert or notification for medical providers is entered into the progress notes, and CPS medical providers often were not aware that patients' test results were in the system and did not review the information for any medical management of the patient.

226. For established patients at the Alton clinic, providers or clinical staff are instructed to review the files of all patients the night before they were scheduled for an office visit to see if patients have received a test or not. For established patients who have not received iPad testing, physician assistants were instructed to order the tests.

227. CPS providers billed psychological tests to federal, state, and private payors using CPT code 96103, psychological testing by computer, including time for the physician or psychologist to interpret the test. The average Medicare reimbursement for CPT code 96103 in 2015 was $28 per test.

228. It was known within CPS, that patient claims will be coded so as to justify reimbursement for the psychological tests even when medical necessity was not satisfied. A CPS coder, Pam Coleson, described how she would review progress notes after a patient visit to find something to justify reimbursement for the psychological tests.

229. For example, to receive reimbursement for the iPad tests, one diagnosis that could be used was insomnia and, therefore, Coleson's job was to "scrub" the progress notes to see if the patient had admitted to difficulty sleeping at times and to code a diagnosis of insomnia based on the note.

230. After this conversation, Relator grew uncomfortable with ordering the iPad tests. Around mid-April 2015, Relator told her manager, Toni Anderson, that she thought the tests were unnecessary and that she would not order them anymore. Anderson told Relator that she would be reprimanded. Despite this, Relator stopped ordering iPad tests on her patients.

231. To keep up a high volume of iPad testing and generate Medicare reimbursement, CPS threatened to dock bonuses for CPS staff, monitors how many tests each CPS office administered, and offered kickback bonus incentives for administering the tests, in violation of the Anti-Kickback Statute.

232. A December 7, 2015 email about the iPad testing from Sara Trent, CPS Director of Quality Assurance, to CPS providers and staff, stressed that CPS staff should "be advised that CPS standard is to employ this tool and non-participation will not be accepted any longer." The email ends with a threatening reminder that "utilizing any of the resources that CPS makes available to us in managing our patients comprehensively does assist with your bonus at the quarterly true up – however, failure to be comprehensive in your approach to patient care can negatively impact this."

233. On March 24, 2015, Kim Pennington, CPS's Director of Site Operations emailed CPS managers to again urge them to use the iPad tests for all patients and to remind providers and clinical staff that the number of tests they administered was watched closely. She wrote that "[t]his testing serves as a type of risk assessment for all new patients coming into CPS (PMQ-R) and depression screening CCESD-R is often used at the follow-up

visit. Repeat testing is typically indicated as a recommendation on the results." Pennington couched CPS's message to test all patients as often as possible by stating that "Please understand that CPS is in no way encouraging or promoting **misuse** of any of these or other therapy options, but does encourage proper usage of this testing," but directly followed with a threat to dock bonuses: "Please note: If your providers do not choose to utilize these services, John will be asking them the reasons at their evaluations. Quarterly bonuses may be negatively affected as well over time." Pennington also included a list of CPS locations' iPad testing numbers for January and February 2015 per clinic.

234. The highest number of iPad tests administered during that period was 2,150 tests administered at the Oak Ridge, Tennessee location.

235. In June 2016, CPS corporate management made the decision to close thirteen CPS offices due to decreased revenue. In discussing the changes and how CPS intended to become financially stable again, CEO John Davis urged CPS providers and staff to bill more tests and services, including iPad testing, with the following bolded language: **"You can make an immediate impact by being diligent about following the procedures we put in place and by looking for opportunities to utilize the innovative services (CCM/CPS Cares, Pharmacy Services, Renua, Laboratory Panels, Psychological testing, etc.) we have available for our patients, when appropriate, at the discretion of the provider. It is imperative."**

236. In order to encourage screening all patients using these iPad tests, CPS paid a kickback to the ordering provider or staff member in the form of a bonus of $5-10, depending on the year, per IPad test.

237. Defendants knew its policy and practices of administering as many iPad tests as possible, including repeated testing on patients, did not comply with conditions of reimbursement but ignored these requirements in favor of generating maximum revenue.

238. Defendants submitted false or fraudulent claims for unnecessary psychological tests for payment to Medicare, Medicaid, and other insurers.

E. Defendants Pressured Providers to Code Physical Examinations of Patients Higher in Order to Receive Greater Reimbursement from Medicare and Medicaid

239. In addition to indiscriminate and repeated testing of patients, CPS pressured its providers to "upcode" the Evaluation and Management codes for office visits even when services consistent with that code had not been rendered.

240. Specifically, CPS pressured clinical staff to code all office visits with the 99214 Evaluation and Management code for established visits.

241. Relator observed during her time at CPS that providers and/or clinical staff often did not actually perform the level of service necessary to warrant using CPT code 99214.

242. Patient visits billed to CPT code 99214 require more complexity than those billed to 99213. Two of the three following components are required to bill an established patient visit with a 99214 CPT code: taking a detailed history of the patient that explores one or multiple chronic illnesses with exacerbation or progression, or three or more self-limiting or minor problems; a moderate level of decision-making involved, involving multiple diagnoses, complex data review, and a moderate risk of complications or side effects; or a detailed physical examination. The face-to-face component of a 99214 visit should be approximately twenty-five minutes long.

243. In Relator's observations, providers—mainly physician assistants who conducted the follow-up visits for established patients—would rarely spend twenty-five minutes with patients, more often spending ten or fifteen minutes with most patients, as well as failing to satisfy other requirements for 99214 billing.

244. In late 2015 and early 2016, CPS's Quality Assurance team reviewed providers' charts to see if they were documenting medical necessity appropriately and to further see whether providers were coding to 99214 with each patient visit as instructed.

245. In addition to reviewing charts to ensure that the documentation would support a 99214 code even if the services had not been performed, CPS urged and threatened providers that they must be billing all established patient visits with CPT code 99214, going so far as to threaten providers' bonuses if they did not use 99214.

246. CPS sent out an "Urgent E&M Memo" to all CPS Providers on January 28, 2016 pressuring and urging providers to only code patient encounters with CPT code 99214 instead of CPT code 99213. The CPS division of Compliance: Quality Assurance & Education informed providers that that "[i]t is imperative that you immediately examine your own Evaluation & Management (E&M) coding practice. The vast majority of our providers are most commonly billing 99213 but are, in fact, meeting 99214 in their documentation. This failure to bill appropriately negative impacts our ability to care for our patients as it limits resources available to hire support staff, providers and improve/maintain working conditions in your office."

247. The January 2016 memo further threatened that "the leaders within CPS will be reviewing for your billing compliance, and warnings, lost bonuses, and other disciplinary actions may be taken if there is no response to this and previous education and information given." In the memo's explanation of how CPS bills patient encounters, Trent wrote that "There is no foreseeable reason that any CPS provider should have less than a comprehensive history while performing an E&M encounter with a chronic pain patient."

248. In addition to making all providers code established patient visits as 99214 visits, providers also used templates in their progress notes, which made it appear as though providers had done a more thorough examination than had actually been performed. During

each appointment providers must record progress notes on the patient's condition and any actions taken by the provider.

249. Providers were encouraged by CPS to "clone" their progress notes by using pre-made templates and copying these templates into the patient's notes on eCW. During Relator's training at CPS, she was taught by another physician assistant to copy and paste notes from a template into each visit's progress notes. Relator noted that the documentation did not reflect the patient's actual condition but instead was used to inflate claims about the complexity or level of services performed.

F. Retaliation Against Relator for Seeking to Prevent Submission of False or Fraudulent Claims

250. Relator raised concerns that there were a number of potential billing irregularities at CPS. In early May 2015, Relator asked the Practice Manager, Toni Anderson, if Anderson could arrange a meeting to discuss how everyone should be reviewing the drug screens and making sure medication lists were accurate, the issues with progress notes, and with work flow in general at CPS.

251. On May 6, 2015, Anderson arranged a meeting, attended by the physician assistants, medical assistants, Specimen Collector Roni Cherry, Coder Pam Coleson, and a nurse practitioner.

252. Instead of directing and running the meeting herself, Anderson put Relator on the spot and told her to run the meeting, as well as making it seem as though the meeting was called just to appease Relator, and that her complaints were unreasonable.

253. Several days after the meeting, Relator spoke with the Vice President of Business Development at CPS, Bo Boyer. She explained that she was being singled out in part for bringing up her concerns. Boyer acknowledged that Anderson was treating her

unfairly. He asked Relator to call him again if the situation did not improve within a few weeks.

254. On May 29, 2015 Relator was told to stop working at the Alton clinic without warning and she was sent home by Practice Manager Anderson to wait and receive further instructions from CPS corporate.

255. On June 3, she was informed that she was relieved of her job duties and terminated.

256. Relator alleges that her termination was retaliatory for Relator's efforts to prevent overbilling of Medicare, Medicaid, and other state and federal health programs.

257. As set forth herein, and supported by Relator's good faith investigation and review of relevant documents and witness information, Relator alleges that CPS knowingly has caused, and continues to cause, the submission of false or fraudulent claims to federal and state health programs and private payors in Illinois.

VII. CAUSES OF ACTION

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), (B), & (G)

258. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

259. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

260. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval, in violation of 31 U.S.C.§ 3729(a)(1)(A).

261. By and through the acts described above, Defendants have knowingly made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C.§ 3729(a)(1)(B).

262. By and through the acts described above, Defendants knowingly concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the Government, 31 U.S.C.§ 3729(a)(1)(G).

263. The Government, unaware of the falsity of all such claims made or caused to be made by Defendants, has paid and continues to pay such false or fraudulent claims that would not be paid but for Defendants' illegal conduct.

264. By reason of Defendants' acts, the United States has been damaged in a substantial amount to be determined at trial.

265. Additionally, the United States is entitled to the maximum penalty of up to $21,563 for each and every violation alleged herein, or for violations occurring on or prior to November 2, 2015, the maximum penalty of up to $11,000.

Count II
Federal False Claims
Retaliatory Discharge of Relator Chancellor
in Violation of the Anti-Retaliation Provision
of the False Claims Act
31 U.S.C. § 3730(h)

266. Relator realleges and incorporate by reference the allegations contained in paragraphs 1 through 253 above as though fully set forth herein.

267. Relator Chancellor objected to CPS's policies and procedures requiring performance of unnecessary laboratory and other testing and submission of claims for those unnecessary tests to federal, state, and private payors.

268. Relator Chancellor's efforts were lawful acts in furtherance of her efforts to stop or prevent a violation by Defendant CPS of the provisions of Title 31, Chapter 37, Subchapter III of the United States Code.

269. Substantial and motivating factors, but for which Relator Chancellor's employment would not have been terminated by Defendants, included her lawful acts in furtherance of her efforts to stop or prevent a violation by Defendants of the provisions of Title 31, Chapter 37, Subchapter III of the United States Code.

270. Relator Chancellor's termination was in violation of 31 U.S.C. 3730(h).

Count III
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §§ 175/3(a)(1)(A)–(B), (G)

271. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

272. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

273. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

274. By virtue of the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the Illinois State Government.

275. Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

276. The Illinois State Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

277. Defendants have damaged the State of Illinois in a substantial amount to be determined at trial.

278. Additionally, the Illinois State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count IV
Illinois Insurance Claims Fraud Prevention Act
740 Ill. Comp. Stat. § 92

279. Relator repeats and realleges each and every allegation contained in paragraphs 1-253 above as though fully set forth herein.

280. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92.

281. Subsection 5(b) of the Illinois Insurance Claims Fraud Prevention Act provides:

> A person who violates any provision of this Act or Article 46 of the Criminal Code of 1961 shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.

282. Article 46 of the Illinois Criminal Code, referenced in the above-quoted section, provides criminal penalties for any person who commits the offense of insurance fraud, defined in the statute as follows:

> (a) A person commits the offense of insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control

> of the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claims to be made on any policy of insurance issued by an insurance company. . ..

720 Ill. Comp. Stat. § 5/46-1(a).

283. Subsection 15(a) of the Illinois Insurance Claims Fraud Prevention Act provides for a qui tam civil action in order to create incentives for private individuals to prosecute violations of the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for violation of this Act for the person and for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. § 92/15(a).

284. By virtue of the conduct described in this Complaint, defendant committed the following acts, or aided and abetted the commission of the following acts, in violation of the Illinois Insurance Claims Fraud Prevention Act: knowingly obtained, attempted to obtain, or caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat. § 92/5(b) and 720 Ill. Comp. Stat. § 5/46-1(a).

285. As a result of such conduct, Defendants received illegal profits to which it was not entitled, at the expense of insurers and at the expense of the People of the State of Illinois, in a substantial amount to be determined at trial.

286. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by defendant in violation of 740 Ill. Comp. Stat. § 92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count V
Indiana Medicaid False Claims and Whistleblower Protection Act

Ind. Code §§ 5-11-5.7-2(a)(1) -(2), (6)(B)

287. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

288. This is a claim for treble damages and penalties under the Indiana Medicaid False Claims and Whistleblower Protection Act.

289. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval.

290. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, material to false and fraudulent claims.

291. By virtue of the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the State of Indiana.

Count VI
Iowa False Claims Act
Iowa Code §§ 685.2(1)(a)–(b), (g)

292. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

293. This is a claim for treble damages and penalties under the Iowa False Claims Act.

294. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

295. By virtue of the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the Iowa State Government.

296. Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Iowa State Government to approve and pay such false and fraudulent claims.

297. The Iowa State Government, unaware of the falsity of the records, statements, and claims that Defendant made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

298. Defendants have damaged, and continues to damage, the State of Iowa in a substantial amount to be determined at trial.

299. Additionally, the Iowa State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count VII
North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-607(a)(1)– (2), (7)

300. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

301. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

302. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

303. By virtue of the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the North Carolina State Government.

304. Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

305. The North Carolina State Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

306. Defendants have damaged the State of North Carolina in a substantial amount to be determined at trial.

307. Additionally, the North Carolina State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count VIII
Tennessee False Claims Act and Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a)(1)– (2), (7) and §§ 71-5-182(a)(1)(A)–(B), (D)

308. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

309. This is a claim for treble damages and penalties under Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

310. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

311. By virtue of the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the Tennessee State Government.

312. Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

313. Relator cannot now identify all of the false claims for payment that Defendants' conduct caused, as numerous separate entities across the state presented the false claims. Relator has no control over such entities and no access to records they possess.

314. The Tennessee State Government, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

315. Defendant have damaged the State of Tennessee in a substantial amount to be determined at trial.

316. Additionally, the Tennessee State Government is entitled to the maximum penalties pursuant to the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act for each and every violation alleged herein.

Count IX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.3(A)(1) -(2), and (7)

317. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-253 above as though fully set forth herein.

318. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

319. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval.

320. By virtue of the acts described above, Defendants knowingly concealed and improperly avoided or decreased an obligation to pay money to the Virginia State Government.

321. The Virginia State Government, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be made, used, or presented by Defendants paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

322. By reason of Defendants' acts, the Virginia State Government has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

323. Additionally, the Virginia State Government is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

VIII. PRAYER

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729, *et seq.*;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $10,781 and not more than $21,563 for each violation of 31 U.S.C. § 3729;

3. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal False Claims Act; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/3(a)(1)(A)-(B); Illinois Insurance Claims Fraud Prevention Act 740 Ill. Comp. Stat. § 92,; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7 *et seq.* (as amended through P.L. 109-2014); Iowa False Claims Act, Iowa Code §§ 685.2(1)(a)–(b), (g); North Carolina Medicaid False Claims Statute, N.C. Gen. Stat. §§ 1-607(a)(1)–(2); Tennessee False Claims Act and Tennessee Medicaid False

Claims Act, Tenn. Code Ann. §§ 4-18-103(a)(1)–(2) and §§ 71-5-182(a)(1)(A)–(B); Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.3(A)(1)-(2), and (7).

4. That this Court enter judgment against Defendants in an amount equal to three times the amount of each claim for compensation submitted by Defendants in violation of the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92 *et seq.*, and that 0 Ill. Comp. Stat. § 92, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 92 and that Relator be awarded the maximum amount allowed under the Illinois Insurance Claims Fraud Prevention Act.

5. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

6. That the United States, the Plaintiff States, and Plaintiff-Relator recover such other and further relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: July 22, 2019

Respectfully submitted,

Richard A. Fisher/s

Richard Fisher
Richard Fisher Law Firm
1008 Tasso Road NE
Cleveland, TN 37323
Tel: (423) 479-7009
Fax: (423) 614-6807
Richardfisher4@cs.com

Colette G. Matzzie
Amy Easton
Phillips & Cohen LLP
2000 Massachusetts Ave NW
Washington DC, 20036
Tel: (202) 833-4567
Fax: (415) 836-9001
cmatzzie@phillipsandcohen.com
aeaston@ phillipsandcohen.com

Emily Stabile
Phillips & Cohen, LLP
100 the Embarcadero, Suite 300
San Francisco, California 94105
Tel: (415) 836-9000
estabile@pcsf.com

Sean Estes
Hoyer Law Group, PLLC
2801 W. Busch Blvd., Ste. 200
Tampa, FL 33618
Tel: (813) 375-3756
sean@hoyerlawgroup.com

Attorneys for *Qui Tam* Plaintiff Allison Chancellor

Addendum A to Complaint

The following pharmacogenetics tests were performed by CPS on patients:

a. Apolipoprotein E: This gene is associated with risk of cardiovascular disease and late-onset Alzheimer's disease. No LCDs cover Apolipoprotein E as medically necessary for cardiovascular or other reasons. *See* MolDX: Biomarkers in Cardiovascular Risk Assessment (L36139), CGS Administrators, LCC (Oct. 5, 2015) (covering Kentucky and Ohio); MolDX: Biomarkers in Cardiovascular Risk Assessment (L36129), Palmetto GBA (Oct. 5, 2015) (covering Virginia, South Carolina, North Carolina); MolDX: Biomarkers in Cardiovascular Risk Assessment (L36523), Wisconsin Physicians Service Insurance Corp. (June 16, 2016) (covering Alabama, Arkansas, Illinois, Indiana, Kentucky, Louisiana, Mississippi, North Carolina, Ohio, South Carolina, Tennessee, and Virginia). MolDX: ApoE Genotype Coding and Billing Guidelines (A54244), CGS Administrators, LLC (Oct. 1, 2015) (covering Kentucky, and Ohio); ApoE Genotype Coding and Billing Guidelines (A53652), Palmetto GBA (Oct. 1, 2015) (covering South Carolina, North Carolina, and Virginia).

b. COMT: This gene is associated with the dopamine and norepinephrine transmission in the brain which may impact schizophrenia and may be involved with risk factors for bipolar disorder, panic disorder, anxiety, obsessive-compulsive disorder, eating disorders, and attention deficit hyperactivity disorder. This test is not considered medically necessary by those MACs that have addressed it and it is not reimbursable. MolDX: CYP Gene Evidence Analysis (A54704), GCS Administrators, LLC (Oct. 15, 2015) (covering Kentucky and Ohio); MolDX: CYP Gene Evidence Analysis (A54701), Palmetto GBA (Oct. 15, 2015) (covering South Carolina, Virginia, and North Carolina).

c. CYP2B6: This gene encodes variations that may impact the absorption of and concentration of Methadone in the blood. Although there are no LCDs for the CYP2B6 PGT test, the MACs Palmetto GBA and CGS Administrators have issued a Medicare Coverage Article regarding CYP2B6 testing and billing which states that this test is a statutorily excluded service and is not covered. MolDX: CYP2B6 Test Coding and Billing Guidelines (A54260), CGS Administrators, LLC (Oct. 1, 2015) (covering Kentucky and Ohio); MolDX: CYP2B6 Test Coding and Billing Guidelines (A53556), Palmetto GBA (Oct. 1, 2015) (covering South Carolina, Virginia, and North Carolina).

d. CYP2C19: This gene may influence how a patient metabolizes about 15% of commonly used drugs including several Serotonin inhibitors (SSRI) antidepressant drugs, tetracyclic antidepressants, and benzodiazepines. LCDs have ruled that all PGT testing for these uses is not medically necessary or reasonable and will not be reimbursed by Medicare. Biomarkers Overview (L35062), Novitas Solutions, Inc. (Oct. 1, 2015) (covering Arkansas, Louisiana, and Mississippi). The only use for which this PGT test is indicated as medically necessary is for assessing the absorption rates of patients on the blood thinner Plavix. *Id*. All LCDs follow a similar approach to CYP2C19 testing. *See*, *e.g.*, CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35698), First Coast Service Options, Inc. (Oct. 1, 2015) (covering for Florida, Puerto Rico, and the Virgin Islands); Genetic Testing for CYP2C19, CYP2D6, CYP2C9, and VKORC1 (L36398), Wisconsin Physicians Service Insurance Corp. (April 16, 2016) (covering Alabama, Arkansas, Illinois, Indiana, Kentucky, Louisiana, Mississippi, North Dakota, Ohio, South Carolina, Tennessee, Virginia); MolDX: Biomarkers in Cardiovascular Risk Assessment (DL36360), Noridian Healthcare Solutions, LLC (Proposed/Draft LCD) (covering Alaska, Idaho,

Oregon, Washington, Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming); MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35332), CGS Administrators, LLC (Oct. 1, 2015) (covering Kentucky and Ohio).

e. CYP2C9: The CYP2C9 gene impacts the metabolism of about 15% of commonly prescribed medications, including the depression and epilepsy drugs fluoxetine, phenytoin, primidone, and amitriptyline, among others. Although a National Coverage Determination has been published permitting the use of CYP2C9 testing for cardiovascular patients starting Warfarin (a blood thinner) who are enrolled in a clinical study, all other uses of CYP2C9 genetic testing are considered medically unnecessary. Pharmacogenomic Testing for Warfarin Response (90.1), April 5, 2010; CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35698), First Coast Service Options, Inc. (Oct. 1, 2015) (coverage for Florida, Puerto Rico, and the Virgin Islands); Genetic Testing for CYP2C19, CYP2D6, CYP2C9, and VKORC1 (L36398), Wisconsin Physician Service Insurance Corp. (April 16, 2016) (covering Alabama, Arkansas, Illinois, Indiana, Kentucky, Louisiana, Mississippi, North Dakota, Ohio, South Carolina, Tennessee, Virginia); MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35332), CGS Administrators, LLC (Oct. 1, 2015) (covering Kentucky and Ohio); Pathology and Laboratory: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35660), Cahaba Government Benefit Administrators, LLC (Oct. 1, 2015).

f. CYP2D6: This gene is involved in metabolizing approximately 25% of common medications, including antidepressants and antipsychotics such as desipramine, imipramine, and amitriptyline. It may have some effect on the safety and effectiveness of painkillers like Codeine, Tramadol, Hydrocodone, and Oxycodone. LCDs have determined that, aside from patients tested prior to initiating tricyclic

antidepressant treatment with amitriptyline or nortriptyline, "there is insufficient evidence for *CYP2D6* genotyping for individuals considering antipsychotic medications or other antidepressants with *CYP2D6* as a metabolizing enzyme," thus all other uses are medically unnecessary. Pathology and Laboratory: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35660), Cahaba Government Benefit Administrators, LLC (Oct. 1, 2015) (covering Alabama and Tennessee) (emphasis in original); *see also* CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35698), First Coast Service Options, Inc. (Oct. 1, 2015) (covering Florida, Puerto Rico, and the Virgin Islands); Molecular Pathology Procedures (L35000), National Government Services Inc. (Oct. 1, 2015) (covering Illinois); MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35072), Palmetto GBA (Oct. 1, 2015) (covering Virginia, North Carolina, and South Carolina); Molecular Pathology Procedures (DL35000), National Government Services, Inc. (Proposed/Draft LCD) (covering Illinois).

g. CYP3A4: This gene catalyzes reactions involved in metabolism of drugs including diazepam (Valium). The only LCD published about PGT testing for CYP3A4 indicates that it is medically unnecessary and not covered by Medicare. Molecular Pathology Procedures (L35000), National Government Services, Inc. (Oct. 1, 2015) (covering Illinois).

h. CYP3A5: This gene is one enzyme that assists in metabolizing about 50% of commonly used drugs, notably the painkillers Fentanyl, Oxycodone, Buprenorphine, the anti-anxiety drug Alprazolam (Xanax), the sleep aid Ambien, and the antidepressants nefazodone, trazodone, and vilazodone. The only LCD to specifically address CYP3A5 testing states that this genetic test "will be denied as not medically

necessary." Molecular Pathology Procedures (L35000), National Government Services, Inc. (Oct. 1, 2015) (covering Illinois).

i. SLCO1B1: SLCO1B1 is a protein-coding gene associated with drug metabolism, particularly of statin drugs which are given to patients to help prevent cardiovascular events. The only LCD to address PGT testing for SLCO1B1 determined that it is not medically necessary. Molecular Pathology Procedures (L35000), National Government Services, Inc. (Oct. 1, 2015) (covering Illinois); MolDX: SLCO1B1 Genotype Coding and Billing Guidelines (A54286), CGS Administrators, LLC (Oct. 1, 2015) (covering Kentucky and Ohio); SLCO1B1 Genotype Coding and Billing Guidelines (A53698), Palmetto GBA (Oct. 1, 2015) (covering Virginia, North Carolina, and South Carolina).

j. MTHFR: This gene is tested for two common mutations that may be associated with cardiovascular risk or blood clots, and folic acid absorption. PGT testing for this gene is not covered by Medicare. *See, e.g.*, Biomarkers Overview (L35062), Novitas Solutions, Inc. (Oct. 1, 2015) (covering Arkansas, Louisiana, and Mississippi); MolDX: Biomarkers in Cardiovascular Risk Assessment (L36139), CGS Administrators, LLC (Oct. 5, 2015) (Kentucky and Ohio); MolDX: Biomarkers in Cardiovascular Risk Assessment (L36129), Palmetto GBA (Oct. 5, 2015) (covering Virginia, North Carolina, and South Carolina); Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36400), Wisconsin Physicians Service Insurance Corporation (April 16, 2016) (covering Arkansas, Illinois, Indiana, Kentucky, Louisiana, Ohio, North Carolina, Mississippi, Virginia, and South Carolina).

k. VKORC1: A National Coverage Determination for Pharmacogenomic Testing for Warfarin Response was implemented by CMS that addressed PGT testing for

VKORC1 for Warfarin (a blood thinner) use. It determined that, aside from randomized, controlled clinical studies, testing was medically unnecessary and not covered. Pharmacogenomic Testing for Warfarin Response (90.1), April 5, 2010.